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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,998	05/03/2006	Masahiro Morita	HAYAK-18	4936
23599	7590	10/29/2007	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			SWEET, THOMAS	
		ART UNIT	PAPER NUMBER	
		3774		
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		10/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/577,998	MORITA, MASAHIRO
	Examiner	Art Unit
	Thomas J. Sweet	3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1-14 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 5/3/06 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 05/03/2006

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_.

## **DETAILED ACTION**

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the relationship to the ear must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Specification*

The abstract of the disclosure is objected to because it exceeds 150 words. Correction is required. See MPEP § 608.01(b).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "at least partly in a region, not more than 0.9 mm" after a minimum internal dimension is claim. It is not clear from this passage whether 0.9 mm is the upper limit or the size of a constriction.

Claim 8 recites the limitation "the closer" and "the smaller" in last two lines. There is insufficient antecedent basis for this limitation in the claim. The closer and smaller to what? This is unclear based on the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Litner (US 6589286). Litner discloses an artificial auditory tube (fig.1) consisting of a tubular body having a proximal end (14) fully capable of being placed protruding out of the tympanic membrane within

the external auditory canal (sized such that it would fit and is flexible) and having a distal end (16) to be inserted from the tympanic cavity into the eustachian tube and placed through the isthmus and facing the inside of the cartilaginous eustachian tube (as shown in fig 4),

the distal end and the proximal end communicating with each other through an internal cavity extending in the axial direction of the tubular body,

the internal cavity opening to the outside through a first opening located at or close to the distal end (there are side wall openings all along the tube between the 18s), and

the external cross sectional dimension of the tubular body falling in the range of from 0.35 to 3.0 mm (31, about 2 mm),

wherein the artificial auditory tube includes a second opening defined in the wall of the tubular body and positioned in the region ranging from 9 to 30 mm away from the distal end (there are side wall openings all along the tube between the 18s) and communicating with the internal cavity of the tubular body.

Regarding claim 2, Litner discloses an artificial auditory tube as discussed above the cross sectional dimension of the internal cavity of the tubular body is not less than 0.20 mm and, at least partly in a region, not more than 0.9 mm (e.g. 1mm outside diameter claim 6, knitted wall thickness of 0.2 mm claim 8 is an internal cavity of 0.6 mm).

Regarding claim 3, the artificial auditory tube includes a third opening defined in the wall of the tubular body and positioned in the region that is located between 1 and 16 mm away from the distal end and between 8 and 26 mm toward the distal end away from the second opening, the third opening communicating with the internal cavity of the tubular body (there are side wall openings all along the tube between the 18s).

Regarding claim 4, the tubular body comprises a shaft portion that is a relatively thick tubular portion including a proximal end region (14, flange) fully capable of being placed protruding out of the tympanic membrane within the external auditory canal (these are intended use limitation which are met if the structure is fully capable of the use) and a distal portion that is a relatively thin tubular portion (27) fully capable of extending forward in the axial direction from the shaft portion to be inserted from the tympanic cavity into the eustachian tube through the tympanic opening of the eustachian tube to place the distal end through the isthmus facing the inside of the cartilaginous eustachian tube, and the distal portion forms up to 4-20 mm from the distal end of the artificial auditory tube(27, col 5, lines 6).

Regarding claim 5, the distal portion stepwise or continuously decreases in the external cross sectional dimension thereof along the direction from the proximal end to the distal end thereof relative to the shaft portion (26 to 28 to 27 as in fig. 2).

Regarding claim 6, the cross sectional dimension of the internal cavity of the shaft portion of the tubular body is expanded relative to the cross sectional dimension of the internal cavity of the distal portion of the tubular body (26 is bigger than 27).

Regarding claim 7, the external cross sectional dimension of the artificial auditory tube falls in the range of from 0.35 to 1.7 mm at the position where the first opening is located (col 5, line 7).

Regarding claim 9, the distal portion consists of a forefront tubular portion (27) and an intermediate tubular portion (26 or 28) located between the forefront tubular portion and the shaft portion (14).

Regarding claim 10, the external cross sectional dimension of the intermediate tubular portion differs by at least 0.15 mm from that of the forefront tubular portion and also from that of the shaft portion (the dimensions of the stent varying in keeping with the variable dimensions of the human adult and pediatric, col 4, lines 66-67, which inherently includes a difference of at least 0.15mm., .5 mm according to claim 6).

Regarding claim 11, the ratio in length of the forefront tubular portion (27) to the intermediate tubular portion (26) is 1:2 to 2:1 (10-14mm:10mm, 1:1 to 1.4:1).

Regarding claim 12, the full length thereof is 20 to 70 mm (col 5, line 12).

Regarding claims 13 and 14, made of a flexible material is a synthetic resin (silicon resin for one).

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Litner. Litner discloses an artificial auditory tube as discussed above including the distal portion is made of two or more tubular portions differing in external cross sectional dimension (26,28 and 27) and serially combined (this is a product by process limitation which is rejected on the resulting structure being fully capable of being made by the process) and aligned from the distal extremity of the shaft portion toward the distal end of the artificial auditory tube (as shown in fig. 2), and wherein the closer is a tubular portion to the

distal end, the smaller is the external cross sectional dimension thereof (as best understood this appears to mean the distal most end is the smallest cross section).

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Several references are listed on the enclosed 892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet  
Examiner AU 3774

